

## **SUPPORTING STATEMENT**

**0910-0354**

### **PROCEDURES FOR THE SAFE PROCESSING AND IMPORTING OF FISH AND FISHERY PRODUCTS**

#### **A. Justification**

##### **1. CIRCUMSTANCES AND NECESSITY FOR THE COLLECTION**

Part 123 (21 CFR part 123) requires the use of Hazard Analysis Critical Control Point (HACCP) methods by processors of fish and fishery products that have determined by hazard analysis that their products are susceptible to one or more known food safety hazards. HACCP is a science-based methodology by which processors and manufacturers of seafoods establish and follow a pre-planned sequence of operations and observations (the HACCP plan) designed to avoid one or more specific food safety hazards, and thereby ensure that their products are safe, wholesome, and in compliance with the adulteration provisions (section 402) of the Federal Food, Drug, and Cosmetic Act (the act).

By design, the HACCP method relies heavily on monitoring the critical control points established in the plan, and periodically recording the conditions at control points during the processing operations leading to the finished product. These recorded observations are necessary to verify adherence to the established control conditions during the critical processing operations, and therefore demonstrate that the finished food is safe. Thus, adequate recordkeeping is generally recognized as a necessary component of the HACCP approach, whether the method is adopted voluntarily or as a requirement of a regulatory program. HACCP records may be used at any time after processing to verify that the hazards controlled by the plan are not present in the finished food product. These records are maintained at the processing facility and are available for FDA review, they are not reported to, or normally collected by the agency.

Under the authority of section 704 of the act (21 U.S.C. section 374), FDA periodically inspects the facilities of, and collects samples from, domestic food processors, including seafood processors, to determine whether food is prepared, processed, and packaged in compliance with the adulteration, misbranding (section 403), (21 U.S.C. sections 342 (a)(3) and (a)(4)), and other provisions of the act. FDA also inspects and samples foods imported to the U.S. under the authority of section 801 of the act (21 U.S.C. section 381). Compliance of foods with the act and its derivative regulations can often be established only by costly and statistically imperfect sampling and laboratory testing of finished products for physical, chemical, or microbial defects, depending on the potential hazard of concern. HACCP procedures can largely eliminate the need for extensive testing of finished products. HACCP procedures yield products that are known, with a high degree of confidence, to be free of the hazards controlled by a processor's plan.

Thus, in order to continue to implement the HACCP provisions in part 123 that enable industry as well as FDA to determine whether these foods are safe, FDA requests that the Office of Management and Budget extend the recordkeeping requirements associated with the HACCP and sanitation provisions under part 123.

This information collection is authorized by: 21 U.S.C. 321(n), 343(a), 371(a); National Confectioners vs. Califano, *supra*. 569 F.2d at 694-95 and 21U.S.C. 321, 342, 403, 371, 374, and 42 U.S.C. 264.

## 2. HOW, BY WHOM, AND PURPOSE OF THE INFORMATION

HACCP records are compiled and maintained by seafood processors. These records primarily consist of the values of observations made at selected monitoring points during the processing and packaging operations, as called for in a processor's HACCP plan (e.g., processing times, temperatures, acidity values, etc. as observed at critical control points). The primary purpose of HACCP records is to permit a processor to verify that products have been produced within carefully established processing parameters (critical limits) that ensure that hazards have been avoided. HACCP records are normally reviewed by appropriately trained employees at the end of a production lot or at the end of a day or week of production to verify that control limits have been maintained, or that appropriate corrective actions were taken if the critical limits were not maintained. Such verification activities are essential to ensure that the HACCP system is working as planned.

HACCP places the burden of producing safe products and solving problems squarely on the processor. A specific frequency of data collection is not prescribed in the regulation. The schedule of critical control point observations and recording of data (the frequency of collection) is established by each processor according to factors such as the variability of the process and the proximity of nominal processing values to the control limits established in the HACCP plan. At a minimum, each production lot will have associated HACCP and sanitation records. To be effective, HACCP records must be available for all production lots. When a HACCP program is implemented, it becomes an integral part of the food production process.

Thus, a review of HACCP records, either by the processor or an FDA inspector conducting a periodic establishment inspection, will allow a determination of whether current or any previous production lot has deviated from control conditions and may, as a result, contain a public health hazard. These records are highly beneficial to both the processor and the agency to expeditiously identify questionable production lots.

## 3. THE USE OF INFORMATION COLLECTION TECHNOLOGY

Many of the observations required to document HACCP control point parameters (times, temperatures, acidity, etc.) are amenable to modern data acquisition and processing technology. The agency encourages the application of this technology for monitoring and record keeping

operations to minimize the paperwork burden and labor costs, and also to enhance the organization and retrievability of the records. FDA has made this clear in the records provision of this regulation (§ 123.9(f)), which states that records maintained as computer files are acceptable when controls are implemented to ensure the integrity of the system.

#### 4. NOT A DUPLICATION OF INFORMATION ALREADY AVAILABLE

The mandatory HACCP program represents a new regulatory paradigm. Information similar to the records requested here, in most cases does not exist because few processors of fish and fishery products, apart from those canning low-acid seafoods, use HACCP methods. Moreover, except for the manufacturers of low-acid canned foods, processors that do employ HACCP are not currently required to make their HACCP records available to FDA inspectors for examination.

There is no duplication of effort in this area. Seafood processors that currently use HACCP methods, voluntarily or in accord with State or other federal regulations, are likely to already meet specific hazard avoidance and record keeping requirements, because maintaining records of control point observations is a necessary component of the HACCP method and not unique to part 123. Moreover, seafood processor that currently processes low-acid canned fishery products under the provisions of 21 CFR part 113 are using HACCP procedures and record keeping to avoid the hazard of botulinum toxin that can result from the improper thermal processing of low-acid canned food. These processors are exempted (§ 123.6(e)) from the HACCP requirements of this rule with regard to that specific hazard.

#### 5. SMALL BUSINESSES

FDA recognizes that a substantial proportion of seafood processors affected by this regulation are small businesses, and has kept their particular needs in mind throughout the development of this rule. Small businesses are assisted in the preparation of HACCP plans primarily through the publication of the agency's "Fish and Fishery Products Hazards and Controls Guide." This publication contains model HACCP plans, example forms, and commodity information to assist processors in identifying hazards and suggest preventive measures for their control. FDA also participates in an alliance with industry and academia (The Seafood Alliance) that has designed a curriculum and provided uniform HACCP training nation wide. Moreover, before the effective date of the HACCP rule, FDA inspectors assisted processors that requested that FDA review their plan and procedures, as resources permitted. FDA also provides help to small manufacturers through its Office of Small Manufactures Assistance.

## 6. CONSEQUENCES IF LESS FREQUENT OR NO DATA COLLECTION

The consequences of not renewing the collection of HACCP information (i.e., not requiring seafood processors to maintain HACCP records) will prevent the continued adoption of a meaningful industry-wide HACCP program that has been widely sought by industry and consumer advocates. The adoption of HACCP techniques and the associated recordkeeping requirements is the most effective and efficient way for government and industry to ensure food safety.

Continued U.S. participation in international trade requires that seafood processors certify to their trading partners that the products they export have been processed under HACCP controls. The European Economic Community required this certification beginning in January 1996. Exporting U.S. processors must now obtain a certificate for each shipment and are therefore committed to a successful HACCP program.

Under a HACCP scheme, the frequency of data collection by each processor occurs periodically during daily food processing operations, but that frequency of observation and recording will vary considerably for different processors, depending on the nature and the number of hazards controlled under a HACCP plan. Records "collection" must be continuous once a HACCP plan has been implemented. HACCP has little value if used on a part-time basis, particularly in the context of a regulatory program. In that sense, the "frequency of reporting," that is, the periodic recording and maintaining records of control point observations and related HACCP activities can not be elective, it must continue from day to day. There is no apparent way to minimize the collection burdens short of not implementing a seafood HACCP program.

The agency will not "collect" HACCP records or plans as a routine matter. HACCP records will remain on file at each processing facility and will be examined there periodically by the agency to determine, for example, whether a processor is practicing preventive control measures that are consistent with the hazards presented by the fishery species and processes used. HACCP plans and records will document that the appropriate HACCP control measures are applied and have been used for all production lots. Finally, the records will establish that the firm is continuously producing safe seafood products that are in compliance with the provisions of the FD&C Act.

## 7. SPECIAL CIRCUMSTANCES OF INFORMATION COLLECTION

The collection of HACCP information does not involve submission of information to the agency, written responses to the agency, retention of records for more than three years, the use of statistical methods, pledges of confidentiality by FDA, or require the disclosure of trade secrets or other confidential information. Although some of the respondents believe that HACCP records that may be copied by the agency in pursuit of compliance action against unsafe foods may contain proprietary business information. As discussed below, FDA attempts to safeguard information of this nature from public disclosure.

## 8. SOLICITATION OF COMMENTS AND OUTSIDE CONSULTATIONS

FDA published a notice of proposed rulemaking on January 28, 1994 in the Federal Register (59 FR 4142). FDA reviewed the three comments to the proposal that specifically addressed paperwork reduction issues in the paperwork reduction section of the final rule, which published on December 18, 1995 (60 FR 65096). A copy of final rule is attached. As discussed therein, FDA significantly revised its assessment of the paperwork burden from the original presented in the proposal.

FDA has for a number of years actively explored the feasibility of the adoption of HACCP methods by the seafood industry. The agency has consulted extensively with the National Marine Fisheries Service (NMFS). Both FDA and the NMFS have conducted a voluntary pilot HACCP program with participants from different segments of the seafood industry. In addition, in recent years FDA has consulted with industry representatives, including those of the National Fisheries Institute (NFI), and obtained views on a broad range of issues related to the application of HACCP methods by seafood processors, including its desirability, selection of critical control points, data collection, types of data, and recordkeeping requirements. Various leaders of the seafood industry have called for a mandatory HACCP program.

Shortly after the publication of the proposed HACCP rule, and again following publication of the final rule, agency representatives held "town hall" meetings in nine major cities across the U.S. to advise, interpret, and hear views from all interested sectors. However, it is the approximately 300 written responses to the published proposal that serve as the agency's primary detailed source of outside views with regard to all of the issues raised by the HACCP proposal, including the recordkeeping provisions.

The great majority of the written comments supported the HACCP concept for seafoods. Virtually none of the comments argued that HACCP records should not be maintained, although a minority of the comments that addressed records and recordkeeping argued that FDA should require that processors record only "negative" events, i.e., record only those cases when deviations from critical limits have occurred, rather than recording the control point values at all observations. The agency has considered and rejected this approach because it would not allow processors and FDA to retrospectively verify that the HACCP system was functioning as planned and that the potential food hazards thereby avoided.

Few of those commenting on the published proposal specifically addressed the agency's estimate of the annual number of hours that a processor will expend on the recordkeeping. One comment estimated that the burden would vary from 200 to over 700 hours, depending on the type of product; another comment stated that the agency's estimate of 650 hours was reasonable for a plant operating for ten months each year but the amount would be proportionately higher for firms with more than one facility. A third comment suggested that one hour per day, or 365 hours per year would be required, while another comment estimated four to five hours per day, or 1,820 hours per year as the likely burden. None of these comments, however, provided information or data to support how they arrived at their estimates.

When viewed in terms of the possible variation in the recordkeeping burden, depending on the size of the firm and the number of products and HACCP operations, the burden figures in the comments are not widely different from FDA's published estimate of an average annual paperwork burden of 650 hours per respondent. This estimate of the burden was made by combining separate estimates for large and small processors. In making that estimate, however, the agency included time spent on activities performed by processors that are beyond the scope of producing a record, such as monitoring the performance of the processing operations at critical control points, the key to the HACCP processing environment. The agency believes that the estimates in the comments are based upon the same misunderstanding, i.e., that these estimates include activities that are not strictly related to the paperwork burden as the agency now understands it.

Other comments addressed virtually every aspect of the proposed HACCP program, but rarely specifically in terms of the recordkeeping burden hours per se. As indicated, comments generally argued, for example, pro or con on the specific HACCP procedures proposed, the types of records to be maintained, whether they should include sanitation, or the proposed period of time that records should be kept after collection.

The potential public disclosure of HACCP records was discussed in a significant number of written comments. Processors are generally concerned that proprietary information will be released, while consumer groups believe that virtually all information related to food safety should be available to the public. The agency has attempted to maintain an equitable position consistent with its disclosure regulations and the public interest. Thus § 123.8(d) states that HACCP plans and records required by part 123 are not available for public disclosure unless they have been previously disclosed, and that HACCP records may be subject to the discretionary disclosure provisions of § 20.82 to the extent that they contain materials that are otherwise publicly available or could not reasonably be expected to cause a competitive hardship if revealed.

There was little or no comment on issues such as the "availability of data", "frequency of collection", the "clarity of instructions", or the "reporting format", as these factors are either not relevant to the HACCP records at issue or generally follow from the design and purpose of the HACCP plan, in which each processor has considerable latitude to work out the details of monitoring techniques, frequency of observations, reporting format, etc. This is not to say that some of the comments did not request clarification of a number of issues in the proposal, particularly with regard to the meaning of certain definitions.

We are not aware that any comments were submitted to the Office of Management and Budget following the publication of the last estimate of recordkeeping burden and request for comments on October 31, 1997 (62 FR 58973).

In accordance with 5 CFR 1320.8(d), on Friday, July 21, 2000, (65 FR 45382), a 60-day notice for public comment was published in the Federal Register. No comments were received from the public.

## 9. PAYMENT OR GIFTS TO RESPONDENTS

Not applicable; this information collection will not provide for any type of payment of gift to respondents.

#### 10. CONFIDENTIALITY PROVIDED RESPONDENTS

Company records describing manufacturing procedures, which may be consulted during FDA plant inspections, are subject to the confidentiality guidelines in 21 CFR Part 20. HACCP plans and records that the agency may copy or take possession of will be treated as records that are exempt from release under the provisions of the Freedom of Information Act to the maximum extent permitted by that statute and FDA regulations.

In the final rule, paragraph (d) of section 123.8, Records, states that "all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter.."

#### 11. SENSITIVE QUESTIONS

There will be no questions of a personally sensitive nature associated with the data collected. All records bear upon conditions under which a food was processed and any corrective actions taken upon the detection of deviations from critical control point conditions.

## 12. ESTIMATES OF THE HOUR BURDEN TO THE COLLECTION

Estimated Annual Recordkeeping Burden <sup>1,5</sup>						
CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping <sup>1</sup>	Total Annual Records	Hours per Recordkeeper <sup>2</sup>	Total Hours	Total Operating & Maintenance Costs
123.6(a),(b),(c)	243	1	243	16.00	3888	\$58,320.00
123.6(c)(5)	4,850	4	19400	0.30	5820	\$87,300.00
123.8(a)(1),(c)	4,850	1	4850	4.00	19400	\$291,000.00
123.12(a)(2)(ii)	1,000	80	80000	0.20	16000	\$240,000.00
123.6(c)(7)	4,850	280	1358000	0.30	407400	\$6,111,000.00
123.7(d)	1,940	4	7760	0.10	1940	\$29,100.00
123.8(d)	4,850	47	227950	0.10	22795	\$341,925.00
123.11(c)	4,850	280	1358000	0.10	135800	\$2,037,000.00
123.12(c)	1,000	80	80000	0.10	8000	\$120,000.00
123.12(a)(2)	50	1	50	4.00	200	\$6,000.00
123.10	243	1	24	24.00	5832	\$87,480.00
Annual burden hours .....627,075						\$9,406,125.00

The above estimates include the information collection requirements in the following sections:

- 123.16 - Smoked Fish- process controls (see 123.6(b))
- 123.28(a) - Source Controls- Molluscan Shellfish (see 123.6(b))
- 123.28(c),(d) - Records - molluscan shellfish (see 123.6(c)(7))

<sup>1</sup> Based on an estimated 280 working days per year.

<sup>2</sup> Estimated average time per 8 hour work day unless one time response

As discussed above, the HACCP program involves recording data related to food processing and sanitation, but it does not require any reporting of this data to FDA or any other government agency. Therefore, only the burden for data collection is considered.



Table 1, sets forth an estimate of the annual hourly burden for compliance with each section in part 123 that is associated with collecting or recording information, including the time required for training (§ 123.10). For example, the entries under "Hours per Recordkeeper" are estimates of the time required for activities such as plan preparation, observation of a processing parameter or condition and recording the observation.

Part 123 also places a paperwork burden on seafood importers (§ 123.12 (a)(2)). For this reason, FDA has estimated a burden for importers that includes the time necessary for importers to develop a written verification plan, verify compliance of imports, and to maintain records of their verification activities.

Processors of fishery products include both large corporations and very small businesses, producing a diversified variety of fishery products, some on only a seasonal basis. Therefore, HACCP record keeping burdens will differ widely among processors, depending on the size of the facility and complexity of the HACCP control scheme (i.e., the number of products and the number of hazards controlled); the daily frequency that control points are monitored and values recorded; and also on the extent that data recording time and cost are minimized by the use of automated data logging technology. The estimated collection burdens were modeled on the operations of a typical small seafood processing facility, which form a significant portion of the seafood industry.

Estimates for the on-going annual burden now assume that only five percent of all processor will prepare a HACCP plan each year, and that the same percentage of all importers will require new or revised product safety specifications. However, the rulemaking exempts any processor from preparing a HACCP plan if a hazard analysis demonstrates that none of the hazards identified in § 123.6 are likely to occur in the fish or fishery product at issue. In addition, § 123.12(a) exempts importers from verification requirements if the imports originate in a country with which FDA has established an MOU. As a result of these exemptions FDA believes that many processors and perhaps a majority of importers will be relieved of significant portions of the estimated paperwork burden. As of June 2000, however, FDA has not finalized an MOU with any country.

The burden hours in Table 1, include only that portion of the compliance burden that may be regarded as a new information collection or recordkeeping requirement under part 123. On a continuing basis, this burden is largely the requirement to record the processing conditions at specific locations in the facility and the regular review of these records.

Thus, where an activity is required under existing regulations the costs of these activities are not considered as a new burden arising from this rule. For example, the Current Good Manufacturing Practices provisions in 21 CFR part 110, already require that all food processors ensure good sanitary practices and conditions, monitor the quality of incoming materials, monitor and control food temperatures to prevent bacterial growth, and perform certain corrective actions and verification procedures. In addition, the tagging and labeling of molluscan shellfish (§ 1240.60) is a customary and usual practice under the purview of the National Shellfish Sanitation Program and as described in a Memorandum of Understanding with FDA.

The total annual burden on processors and importers for the recordkeeping requirements contained in 21 CFR Part 123 is estimated to be 627,075 hours.. This estimate includes a continuing burden (for 5% of all relevant recordkeepers) for one-time activities such as the initial preparation of a HACCP plan, employee HACCP training, and importer product specifications for new processors and importers or the need to modify these records because of changes in the nature of the seafood products processed or imported.

The agency received no comments to the recalculated burden hour estimates published in the final rule (60 FR 65178, Dec 18, 1995), or to any issue related to records and recordkeeping.

### 13. ANNUAL COST BURDEN TO RESPONDENTS

FDA estimates that there are no significant capital costs or operating and maintenance costs associated with this collection. There may be incidental costs such as those associated with the storage of records. Some of these may be for the elective purchase of various components of automated data collection hardware. However, such systems are not required. Costs were estimated for the collection of HACCP data for each type of recordkeeping activity using a labor cost of \$15.00 per hour.

### 14. ESTIMATE OF ANNUALIZED COST TO THE FEDERAL GOVERNMENT

The agency estimates that the annualized cost to the Federal Government for the review and evaluation of the records generated under this proposed rule will not significantly increase the current annual expenditures for ongoing food establishment inspections.

### 15. CHANGES OF ADJUSTMENTS IN BURDEN

The total annual burden hours in the previous information collection included a one time burden of 56,080. This request does not include those burden hours.

### 16. STATISTICAL ANALYSIS, PUBLICATION PLANS, AND SCHEDULE

Not Applicable. This information will not be published, nor will the diverse types of processing data collected be of a nature that lends itself to analysis or publication.

## 17. APPROVAL NOT TO DISPLAY EXPIRATION DATE

There are no reasons why display of the expiration date for OMB approval of the Information Collection would be inappropriate. However, under the conditions applicable to the HACCP information collection, wherein each processor retains the collected data in a format that is unique to his own operations, it would not be feasible to provide this information because no standard forms or questionnaires are provided to the respondents. Moreover, it is anticipated that the HACCP program will be ongoing under appropriate reauthorizations from OMB to continue the information collection because of its importance to the public health.

## 18. EXCEPTIONS TO ITEM 19 IN THE CERTIFICATION STATEMENT

- (a) The collections is necessary for the proper performance of the functions of the agency.

As explained in some detail in the HACCP proposal, although FDA has successfully carried out its responsibilities under the Federal Food, Drug, and Cosmetic Act and its predecessors for a century without HACCP, diminishing federal resources and an ever expanding range of foods, processors, importers and agency responsibilities threaten FDA's ability to efficiently continue to do so in the future. Moreover, food safety experts agree that continuing protection of the public health requires that food safety be controlled by a scientific methodology such as HACCP.

Therefore, except for the enforcement of part 123, it would be somewhat misleading to certify that FDA currently needs the records associated with the HACCP collection for "the proper performance of the functions of the agency." However, if the HACCP system is to be of value as a regulatory paradigm, it is essential that the proposed collection be approved. Without records and records review, HACCP cannot serve the important role set forth in the rulemaking. In this sense, the collection is necessary for the agency to achieve its future goals of protecting the public health by ensuring that the food supply is safe.

- (g) Informs potential respondents of the information called for under § 1320.8(b)(3)

With regard to the requirement in § 1320.8(b)(3)(vi) that "the fact that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number," FDA cannot certify that this information will be available to all respondents because HACCP does not rely on standard forms or responses to questions posed to the respondent community. Thus, for reasons similar to those stated above under 17, FDA sees no reasonable way to insure that each processor or importer is continually made aware of the applicable OMB control number.

## **B. Collections of Information Employing Statistical Methods**

There are no plans to publish the information collected under the provisions of the seafood HACCP regulation for statistical use. The information collection described in Section A does not employ statistical methods.